FEB 1 5 2001

K010243

510(k) SUMMARY

Device: Tri-Fit Femoral Hip System

Date: 01/23/01

Applicant's name: Corin USA
10500 University Center Drive, Suite 190
Tampa, FL 33612

Phone: (813) 977-4469
Fax: (813) 979-0042

Contact person: Joel Batts, Regulatory Affairs Manager

Classification name: Prosthesis, hip, semi-constrained, metal/polymer, uncemented

Product codes: LWJ

C.F.R. section: not specified

Device class: II

Classification panel: Orthopedic

Indications for use

Tri-Fit Total Hip System is indicated for the relief of pain and restoration of hip function following the effects of osteo, rheumatoid and inflammatory arthritis, post-traumatic disease effects, hip fractures, avascular necrosis and total hip revision. Tri-Fit Hip System components are intended to be used in press-fit applications or with bone cement.

Device description

The Tri-Fit Femoral Stem is a modular stem that accepts femoral heads onto its 12/14 Eurocone male taper (either cobalt-chrome or ceramic femoral heads). The stem

substrate is made from a Ti6Al4V and is proximally coated with commercially pure titanium plasma spray. The stem is available in six (6) sizes ranging from 7.5mm to 20mm distal diameter. Four (4) modifications made to the CTi II femoral stem are comprised in the Tri-Fit femoral stem: Modifications to proximal surface coating, distal surface finish, trunnion dimensions and addition of stem introducer holes. **These changes do not effect the fundamental scientific technology or the indications for use.**

Substantial equivalence basis

The sponsor claims substantial equivalence (SE) of the Tri-Fit femoral stem to the CTi II femoral stem on which the Tri-Fit is based. The Tri-Fit contains four (4) modifications of the original CTi II stem which are as follows:

1. Addition of unalloyed titanium plasma sprayed coating to proximal portion of stem

2. Change 11/13 trunnion taper dimensions to Eurocone 12/14

3. Addition of two holes in the proximal face, lateral to the trunnion for stem introducer instrument attachment

4. Change polished finish of distal stem to shotblast finish

Bench testing was carried out to validate the modifications as determined by the Risk Analysis provided in Section 9. The findings indicate that these design modifications will not change the safety or efficacy of the previous design. Summary results are located in Section 7, pages 1 and 2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Joel K. Batts
Regulatory Affairs Manager
Corin U.S.A.
10500 University Center Drive, Suite 109
Tampa, Florida 33612

Re: K010243
Trade Name: Tri-Fit Femoral Stem
Regulatory Class: II
Product Codes: LWJ and LZO
Dated: January 24, 2001
Received: January 25, 2001

Dear Mr. Batts:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Milhous

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K010243

DEVICE NAME: Tri-Fit Total Hip System

INDICATIONS FOR USE:

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(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010243